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October 9, 2019

**VIA ECF**
Honorable Joel Schneider
United States Magistrate Judge
U.S. District Court - District of New Jersey
Mitchell S. Cohen Building & US Courthouse
1 John F. Gerry Plaza, Courtroom 3C
4th and Cooper Streets
Camden, New Jersey 08101

Re: IN RE: VALSARTAN N-NITROSODIMETHYLAMINE (NDMA) PRODUCTS LIABILITY LITIGATION
Civil No. 19-2875 (RBK/JS)

Dear Judge Schneider:

Please accept this letter on behalf of the plaintiffs in advance of the October 10, 2019 telephonic status conference scheduled for 2:00 p.m.

1. **Search Terms and Custodians**

On October 7, 2019, Plaintiffs' counsel, represented by 8 attorneys, met and conferred with counsel for ZHP, Teva, Mylan, Torrent, Aurolife[1], and Hetero USA[2], at the Duane Morris office

[1] Aurobindo, the Indian entity has not yet appeared through counsel.
[2] Defense counsel has not yet confirmed whether they represent the Indian Hetero entities. Counsel for Camber Pharmaceuticals, the US entity which sold and distributed Hetero's products, was not present.

in Philadelphia. The purpose of this meeting was to identify defense custodians and refine search terms. The meeting – most of which focused on ZHP – yielded negligible progress. The most notable take-away was the lack of knowledge or the ability to cooperate on the part of ZHP in particular.

As a threshold matter, not a single Defendant produced an organizational chart or similar document prior to the meeting, despite Plaintiffs' repeated requests, and the obvious usefulness of those documents in identifying necessary custodians. Counsel failed to confirm the existence of organizational charts or even departmental employee lists, HR employee lists, or similar source materials, though now Teva, Aurolife and Torrent have stated an intention to provide certain departmental organization charts within a few days. In stark contrast, ZHP has advised that since organizational charts were formally requested in Plaintiffs' Requests for the Production of Documents ("RFPDs") (the responses and objections to which Plaintiffs' counsel will not even receive until next week), the proper context to discuss whether and which organization charts ZHP will produce should only occur in the context of discussing the RFPDs more generally, the production of which will occur months from now. This sharply increased the inefficiency of the meeting, and was contrary to the spirit if not the letter of the Court's direction that the parties engage in frank and fulsome discussions about custodians.

ZHP has not been forthcoming in its sparse identification of custodians, failing to identify or to be conversant with names, titles, and responsibilities of seemingly important individuals, many of whom were identified by Plaintiffs. ZHP's counsel was unwilling or unable to provide basic information, such as the scope of their knowledge, their roles and responsibilities over time, how their documents are maintained, or even whether these individuals speak English.

After initially identifying a mere seven custodians prior to the meeting, and then two or three additional custodians based on Plaintiffs' questioning during the meeting, ZHP's counsel requested that Plaintiffs identify anyone who Plaintiffs thought might be an appropriate ZHP custodian. Plaintiffs identified more than a dozen individuals, based on Plaintiffs' review of ZHP's core discovery production and publicly available information. ZHP's counsel could not speak to nearly any of these individuals' roles or responsibilities. This was troublesome insofar as Plaintiffs identified these ZHP employees based on ZHP's own documents, including ZHP communications (through counsel) with the FDA, or FDA inspection documents (which, among other things, reflect contemporaneous inspection communications FDA personnel had with ZHP personnel and agents), about the valsartan contamination at issue in this case.[3]

ZHP's lack of candor is illustrated by the fact that they did not identify Jun Du as a custodian. Mr. Du is a member of ZHP's Board of Directors[4] and its Executive Vice President[5] as well as the CEO of Huahai US,[6] Prinston,[7] and Solco.[8] Publicly available FDA warning letters to ZHP about the valsartan contamination at issue in this case are addressed to Mr. Du.[9] Plaintiffs effected service on these entities (including ZHP) by personally serving Mr. Du in New Jersey in this very litigation. The failure by ZHP to list Mr. Du is inexplicable.

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[3] Plaintiffs will be prepared to elaborate *in camera* during Thursday's CMC, but cannot do so here because of ZHP's overly broad confidentiality designations.

[4] https://quotes.wsj.com/CN/XSHG/600521/company-people/executive-profile/11562612.

[5] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/zhejiang-huahai-pharmaceutical-566685-11292018.

[6] https://www.linkedin.com/in/jun-du-1244522/.

[7] http://www.prinstonpharm.com/col.jsp?id=111.

[8] https://www.smithdrug.com/uploads/recalls/valsartanEXPANSION.pdf (Mr. Du signed this recall notice as Solco's CEO, see page 6).

[9] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/zhejiang-huahai-pharmaceutical-566685-11292018.

Then, when Plaintiffs asked about Mr. Du, ZHP's counsel claimed Mr. Du did not possess relevant information in this case in any respect – e.g., manufacturing, quality assurance, regulatory, sales, or analytics. When Plaintiffs pressed about specifics, such as whether Mr. Du was present during FDA inspections of ZHP facilities in connection with the contamination at issue, ZHP's counsel was unable or unwilling to confirm or deny.

The FDA's publicly available June 5, 2017 FDA Establishment Inspection Report identifies Mr. Du ***as the most knowledgeable person in the company*** about the valsartan contamination:

> Mr. Du has been with the firm since 2000. His role includes overseeing operations at the firm in the absence of Mr. Baohua Chen, President / General Manager, who is based in the firm's Headquarters (this was explained as he serves the role as Mr. Chen's Deputy). Mr. Du stated he is responsible for dealing / managing operations in the absence of Mr. Chen. **He stated that he is responsible for overseeing all employees and retains the authority to hire/ fire (with approval by HR). Mr. Du was present daily, and provided clarification of the firm's position regarding several concerns, including presenting proposed corrective action.** ***As the most responsible person for the firm, Mr. Du was issued the FDA 483.***[10]

The Court may also recall Mr. Du from a September 12, 2019 Bloomberg article, in which he is quoted as stating that the manufacturing process changes that likely led to the valsartan contamination were instituted to cut costs:

> "The purpose of the change was to save money," Jun Du, vice chairman of Huahai, told an FDA inspector after the [valsartan] recall began last year. "Mr. Du further stated the cost reduction was so significant it is what made it possible for the firm to dominate the

[10] https://assets.bwbx.io/documents/users/iqjWHBFdfxIU/rDjfTi8J7oQg/v0 (see page 5 for the quotation and throughout for references to Du). This report was made public in a January 10, 2019 Bloomberg article: https://www.bloomberg.com/news/features/2019-01-30/chinese-heart-drug-valsartan-recall-shows-fda-inspection-limits.

> world market share," Cheryl Clausen, the inspector, wrote in a 58-page report reviewed by Bloomberg.[11]

The failure to forthrightly disclose such a key custodian completely undermines ZHP's representation that counsel alone could be relied on to provide the needed information in the absence of knowledgeable corporate representatives. Since someone as obviously important as Mr. Du was missing from ZHP's list, and counsel had no knowledge to share as to his role when the parties met, it is likely that other unidentified persons have crucial knowledge or documents.

Equally troubling, ZHP's counsel was not prepared to identify any custodians or discuss the organizational structure of ZHP's downstream finished-dose subsidiaries, Huahai US, Prinston, and Solco.[12] As these are Defendants in the litigation, who played important roles, it was difficult to understand why counsel was completely unprepared to discuss these entities.

Even as to ZHP itself, ZHP's counsel were unable to answer during the in-person meet and confer basic (and, frankly, quite routine and predictable) questions about ZHP, such as:

> (1) Whether ZHP has corporate organization charts or equivalent documents,
>
> (2) Whether ZHP has a list of people in its departments (in lieu of organizational charts),
>
> (3) What non-custodial sources of documents (e.g., central or departmental files) might exist,
>
> (4) Whether proposed custodians have assistants who receive additional communications intended for the custodians,
>
> (5) Which employees communicated with, or were identified as knowledgeable to, the FDA concerning valsartan API contamination;

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[11] https://www.bloomberg.com/news/features/2019-09-12/how-carcinogen-tainted-generic-drug-valsartan-got-past-the-fda.

[12] Indeed, Counsel for ZHP was even unprepared to discuss what function or roles *these companies* had in the larger corporate structure. As one example, when Plaintiffs identified an employee who worked for Huahai US, Counsel could not confirm what functions or responsibility the corporate entity itself had, let alone identify what roles or functions that specific employee had within Huahai US. This is deeply troubling.

(6) Who analyzed the manufacturing change that allegedly resulted in valsartan API contamination,

(7) Who maintains documents concerning any analysis of the manufacturing change that allegedly resulted in valsartan contamination,

(8) Who writes ZHP's standard operating procedures (for manufacturing and quality control),

(9) Who maintains ZHP's standard operating procedures,

(10) What tests did ZHP use that could or did detect nitrosamines in its valsartan API, at any time,

(11) Who conducts those tests,

(12) Who reviews those tests,

(13) Who maintains those tests,

(14) Who decides what to do (if anything) with those tests,

(15) Does ZHP hire any third-party to test its valsartan API,

(16) Which ZHP employees interact with third-party testers,

(17) Who would decide what testing to give to ZHP customers,

(18) Who, (besides a single high-level employee identified by ZHP's counsel) conducted the root-cause investigation into the contamination,

(19) What is the organization, job titles and responsibilities, and tenure within positions for the departments ZHP has identified as potentially relevant,

(20) How does ZHP communicate with Huahai US, Prinston, and Solco; about what; and who does so,

(21) Do ZHP's self-identified custodians speak English,

(22) Who administered the valsartan recall for ZHP, and

(23) What were the responsibilities of generic job titles gleaned by Plaintiffs, such as "analyst."

The process in Benicar is instructive in comparison. There, the plaintiffs already had a large quantity of internal documents from the New Jersey state litigation when the parties met, so the plaintiffs were in a much better position to address custodians and search terms with some knowledge of internal terminology and custodians. Here, the defense has not produced internal documents. What is more, at least one Defendant has redacted its core discovery documents to excise anything that was not a literal communication to/from the FDA; so internal emails *about* the FDA recall are completely redacted, including names of employees. [13] This obviously undercuts the value of core discovery productions for the purpose of identifying custodians. Plaintiffs have requested clearly relevant exemplar documents from the Defendants, so that internal terminology can be reviewed to aid in establishing search terms, and identification of and interactions between key employees can be accessed to aid in identifying custodians.

The sheer quantity of questions that ZHP's counsel could not or would not answer is deeply concerning. Plaintiffs believe corporate representatives from ZHP, Huahai US, Prinston, and Solco should be added to the meet and confer process as soon as possible. Plaintiffs hope that can be avoided with the other Defendants, but it is premature to say whether it can as Plaintiffs scheduled follow-up meetings with the other Defendants for this week. In addition, the large retailers and distributors who remain in the litigation did not participate in the October 7, 2019 meeting, and it is necessary to address those entities as well.

[13] Plaintiffs have repeatedly requested that this Defendant, Teva, produce unredacted versions of these documents (which are redacted internal emails attaching FDA submissions regarding Valsartan) as the internal communications will assist in identifying additional custodians. Indeed, these emails came from the custodial file of Constance Truemper, an employee Teva designated as a potential custodian in their September 23, 2019 submission. But, much like ZHP, Teva has stated that it will *only* produce the full unredacted version of these documents in full once regular document production starts, months from now.

Plaintiffs look forward to discussing the direction of this process with the Court. At the very least, as things stand now, Plaintiffs must be able to add additional custodians as of right (e.g., without good-cause showings) at a later point in the litigation after Defendants produce internal documents, and as depositions proceed. Otherwise, Plaintiffs will be severely prejudiced in their ability to identify key custodians and documents, and necessary deponents.

2. **Hetero and Aurobindo Corporate Representative Depositions**

On October 4, 2019, pursuant to the Court's order, Aurobindo Pharma USA, Inc. and Aurolife Pharma LLC (collectively the "U.S. Aurobindo Entities") served and filed their objections to plaintiffs' notice of deposition pursuant to Federal Rule of Civil Procedure 30(6)(b). The parties met and conferred on October 7, 2019. Counsel for Aurobindo advised that a supplemental response will be provided in the next day or two. Plaintiffs remain hopeful that the U.S. Aurobindo Entities will provide the requested discovery without the need for a deposition.

No response has been received from Hetero USA Inc. However, Plaintiffs believe that Hetero Labs, Ltd. and Hetero Drugs Limited have been served based on counsel for Hetero USA's stating that one or both of the Indian entities received a copy of a complaint in this case.

3. **"Macro" Discovery Issues**

Plaintiffs are in the process of identifying "macro" discovery issues which can be addressed ahead of the December 11, 2019 CMC. While Plaintiffs have some understanding of what may present itself as a "macro" issue right now, they cannot confirm what these issues are until Defendants serve their responses and objections to Plaintiffs' Request for the Production of Documents. Defendants are to serve these responses and objections on October 15, 2019.

4. **Defendant Fact Sheets**

Plaintiffs are revising the proposed defendant fact sheet per the Court's guidance at the last CMC.

5. **General Discovery Requests**

Plaintiffs served discovery requests on August 30, 2019, and are awaiting Defendants' written objections and responses on October 15, 2019.

6. **Third-Party Payor Fact Sheet**

The parties are working on the TPP fact sheet and will be prepared to present any lingering disputes to the Court by the next in-person CMC, although the parties hope to be able to submit an agreed-upon TPP fact sheet before then.

Please advise if Your Honor requires anything further prior to the conference.

Respectfully,

ADAM M. SLATER

AMS/lat

cc: Seth Goldberg, Esq. (via email)